

CMS PROPOSES TO REQUIRE MANUFACTURERS TO DISCLOSE DRUG PRICES IN TV ADS

The Centers for Medicare & Medicaid Services (“CMS”) recently issued a **proposed rule** (“Proposed Rule”) that would require pharmaceutical manufacturers to disclose the list price for a typical course of treatment of prescription drugs and biologics covered by Medicare or Medicaid in direct-to-consumer television advertisements. This policy development comes just two months after the United States House of Representatives voted to remove an amendment to a bill that would have implemented a similar requirement for manufacturers, even though the bipartisan measure had passed in the Senate. This approach reflects a continued effort by CMS to effectuate policy changes related to drug pricing through agency rather than legislative action. CMS seeks additional public feedback about the Proposed Rule, and stakeholders such as pharmacies, health systems, physicians and pharmacists should provide their comments to CMS by **December 17, 2018**.

The Proposed Rule is part of CMS’s attempts to enhance the level of transparency associated with drug costs and further the current administration’s stated agenda to lower prescription drug prices. It also represents a continued effort to implement key elements listed in the **American Patients First blueprint** that the president presented in May 2018. The blueprint outlines strategies for resolving health care problems faced by patients in the United States, concentrating on increasing competition in the marketplace, enhancing opportunities for negotiation, creating incentives for lower list prices and reducing out-of-pocket costs. Aside from the Proposed Rule, the administration also recently unveiled a **proposal** calling for an “**international pricing index**” that would link selected Medicare Part B drug prices to the prices for those drugs in other European countries such as France and Germany. Taken together, stakeholders should expect to see new policy developments in the pharmacy and prescription drug space.

If finalized, the Proposed Rule would impose a regulatory requirement on prescription drug manufacturers to display the wholesale acquisition cost (“WAC”) prices of drugs in their television advertisements.

ANALYSIS AND DISCUSSION

Pharmaceutical manufacturers selling prescription drugs and biological products that are paid for by Medicare or Medicaid would need to include the WAC (“list price”) in any television advertising. The Proposed Rule would apply this requirement to any drug or biological with a list price greater than \$35 for a one-month supply or a usual course of therapy. For instance, a 10-day course of antibiotics that costs \$50 would need to include the price in any television advertisements for that antibiotic.

In its overview of the Proposed Rule, CMS notes that the 10 most commonly advertised drugs have list prices that range from \$535 to \$11,000 per month for a usual course of therapy. These list prices do not take into account other rebates or discounts, such as the discounts negotiated by an insurer or a pharmacy benefit manager (“PBM”). For example, seniors with prescription drug coverage under Medicare Part D may only pay a portion of the list price because they have coinsurance for certain types of drugs. However, even though many may not ultimately pay the list price for drugs, the WAC is still important since it represents the cost if an individual’s insurance does not cover the drug. WAC also often bears an indirect relationship to negotiated point of sale pricing for insured patients. In addition, CMS estimates that 47 percent of Americans have high-deductible health plans, meaning that many will often pay the list price for drugs before their insurance payments begin to pay a share of the drug’s cost.

Proponents of the Proposed Rule cite price transparency, consumer empowerment and the promotion of informed decision-making as key advantages. CMS notes that the inclusion of pricing information balances the influence that direct-to-consumer television advertising has on consumers’ purchasing decisions, since consumers who learn about new drugs on television are more likely to pressure providers to prescribe the advertised drugs. At the same time, some believe that the requirements of the Proposed Rule are insufficient to help consumers make informed decisions because they do not identify the final cost of prescription drugs after insurer and PBM discounts. Additionally, the Proposed Rule does not directly force pharmaceutical manufacturers to charge less for their drugs.

The Proposed Rule does not contemplate any enforcement mechanisms for violations, other than requiring the Secretary of HHS to maintain a public list of the drugs and biological products that are advertised in violation of the requirements. Still, many industry insiders remain

hopeful that the Proposed Rule will help consumers better understand the cost of prescription drugs, a step towards providing additional data points that build a more complete picture of the true cost of health care.

PRACTICAL TAKEAWAYS

Despite a similar price disclosure proposal failing in Congress even after bipartisan support in the Senate, CMS asserted its authority and chose to move the Proposed Rule forward. If finalized, though, there may be legal challenges to the agency's authority to promulgate this rule.

The Proposed Rule represents the Trump administration's continued efforts to tackle drug prices and demonstrates the types of policy alternatives raised to counter information asymmetry in the health care space. With the rapid release of new policies and the ever-changing atmosphere in the prescription drug space, stakeholders at all levels of the industry should remain attuned and seek out opportunities to share their views. These opportunities may include submitting public comments or working with advocacy teams to prepare responses.

CMS encourages interested parties to comment on the Proposed Rule, and stakeholders interested in submitting comments regarding the Proposed Rule should do so **electronically** or by regular or express mail using the addresses given in the Proposed Rule. Any public comments submitted must be received no later than **5 PM on December 17, 2018**.

As mentioned in recent articles related to proposed changes to **Medicare Part B drug payments, step therapy for Part B drugs** and **developments in the 340B drug discount program**, health care providers, payors, pharmaceutical manufacturers, pharmacies, PBMs and others operating in the drug supply chain should expect additional changes related to prescription drug pricing. The government continues expanding its efforts to lower drug prices, and stakeholders should expect to see more agency regulations and legislative changes that may impact their systems and services.

We will continue monitoring developments in these areas.

If you have any questions or would like additional information about this topic, please contact:

- **Todd A. Nova** at 414-721-0464 or tnova@hallrender.com;
- **Julie K. Lappas** at 317-977-1490 or jlappas@hallrender.com;
- **Kristen H. Chang** at 414-721-0923 or kchang@hallrender.com; and
- Your regular Hall Render attorney.